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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,771	02/12/2004	Geoffrey B. Thrope	9469.18533	2957

26308 7590 11/15/2005

RYAN KROMHOLZ & MANION, S.C.
POST OFFICE BOX 26618
MILWAUKEE, WI 53226

EXAMINER

JOHNSON, SHEVON ELIZABETH

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/777,771	Applicant(s) THROPE ET AL.	
	Examiner Shevon E. Johnson	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/12/2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24 is/are allowed.
- 6) ☒ Claim(s) 1-6, 11, 12, 17, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 7-10, 13-16, and 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/12/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-26, drawn to a neuromuscular stimulation assembly, classified in class 607, subclass 48.
 - II. Claims 27-29, drawn to a percutaneous electrode system, classified in class 600, subclass 374.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are distinct since the percutaneous electrode system may be used as a sterilization device to create scar tissue and produce sterilization in a female patient.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

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inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. During a telephone conversation with Daniel D. Ryan on 11/3/2005 a provisional election was made without traverse to prosecute the invention of a neuromuscular stimulation assembly, claims 1-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-29 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

In regards to claim 1, in line 6, "including an exposed region projecting through an external skin surface" should be "adapted to be projecting through an external skin surface."

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25 and 26 are indefinite in that applicant recites method claims which depend from apparatus claims 1 and 22. As written, these claims are incomplete since they do not disclose any additional structure. If applicant's intent is to present claim 25 as an independent method claim, the Examiner recommends writing out the structural details of claims 1 and 22, rather than making reference to them.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5, 6, 11, 12, 17, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Fang et al. (U.S. Patent Appl. 2002/0077572).

In regards to claim 1, Fang et al. discloses a neuromuscular stimulation assembly 10 (Fig 1A) comprising: at least one electrode 50 sized and configured for implantation in a targeted neural or muscular tissue region (page 3, [0032], Fig. 2), a percutaneous lead 40 electrically coupled to the electrode and including an exposed region projecting through an external skin surface (page 3, [0032], Fig. 2), a carrier 12 sized and configured to be worn on the external skin surface (page 2, [0027], Fig. 1A), circuitry 60 carried on-board the carrier configured to generate a stimulation pulse (page 3, [0035], Fig. 3), and an electrode connection element 30 carried on-board the carrier that is electrically coupled to the circuitry (page 3, [0030], Fig. 3), the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

In regards to claims 2-3 and 5, Fang et al. discloses an assembly comprising a power input bay (noted by cover 16, Fig. 1C) carried on-board the carrier that is electrically coupled to the circuitry, the power input bay being sized and configured to hold a power source 90 (i.e. battery) that can be released and replaced.

In regards to claims 6, 11 and 12, Fang et al. discloses an assembly further comprising a communication means 78 carried on-board the carrier that is electrically coupled to the circuitry, wherein the circuitry includes programmable code 68 that governs generation of the stimulation pulse, the communication bay being sized and configured to establish a communication link between the circuitry and an external device to program the programmable code (page 3, [0037], Fig. 3).

In regards to claim 17, the device of Fang et al. inherently has an electronics bay on-board the carrier to hold the circuitry 60 (page 3, [0035], Fig. 3).

In regards to claims 25 and 26, Fang et al. discloses a method for providing neuromuscular stimulation function includes a function selected from a group comprising (i) maintenance of muscle function; (ii) tissue or bone regeneration; (iii) continuous active motion therapy; (iv) anti-scarring treatment; (v) diagnostic assessment; (vi) neuroplasticity therapy; (vii) anti-spasm therapy; (viii) pain therapy; (ix) post-surgical reconditioning; (x) anti-thrombosis therapy; and (xi) treatment of osteoporosis (page 1, [0001]).

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schouenborg (U.S. Patent No. 5,449,378).

In regards to claim 1, Schouenborg discloses a neuromuscular stimulation assembly (Fig. 1) comprising: at least one electrode 2 sized and configured for implantation in a targeted neural or muscular tissue region (col. 4, lines 19-22), a percutaneous lead 3 electrically coupled to the electrode and including an exposed region projecting through an external skin surface 10, a carrier 1 sized and configured to be worn on the external skin surface 10 (col. 7, lines 38-46), circuitry 4 carried on-board the carrier configured to generate a stimulation pulse (col. 6, lines 49-51), and an electrode connection element 3 carried on-board the carrier that is electrically coupled to the circuitry (col. 4, lines 56-58), the electrode connection

element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region. Note that components electrode 6 and stopper 9 of Schouenborg device can be reconfigure in away that doesn't conflict with applicants claimed invention (col. 5, lines 29-31 and col. 7, lines 20-23).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-5, 17 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benja-Athon (U.S. Patent No. 5,861,015) in view of Chung (U.S. Patent No. 6,338,347) and Lathrop (U.S. Patent No. 5,607,461).

In regards to claim 1-5, Benja-Athon discloses a neuromuscular stimulation assembly (Fig. 1) comprising at least one a percutaneous lead electrically coupled to an electrode 17 or 18 (col. 3, lines 49-67 and col. 4, lines 1-16). Yet, Benja-Athon fails to disclose a detailed description of the system's carrier, circuitry, electrode connection elements, power source (i.e. battery), and power input bay. The Examiner believes that the device may have the above-mentioned components, however, it is also obvious and well known in the art (i.e. electrical stimulators) as taught by Chung and Lathrop. Chung teaches a device comprising a carrier 20/25, circuitry 22 and electrode connection elements 222, battery and power input bay 201 (col. 2, lines 9-21, Fig. 3). Lathrop teaches a device 10 comprising a carrier 12, circuitry 52, electrode connection element 28, battery 50 and power input bay (not shown) (col. 5, lines 1-5, Figs. 1 & 3).

Therefore, it would have been obvious to one of ordinary skill in the art to substitute a common commercially available current generator device as taught by Chung and Lathrop for the stimulus means 16 as disclosed by Benja-Athon (col. 4, lines 2-7).

In regards to claim 17, Benja-Athon discloses a neuromuscular stimulation assembly 1 (Fig. 1) substantially as claimed as stated above except an electronics bay. However, Chung teaches the use of a stimulation assembly comprising an electronics bay 252 (col. 2, lines 34-53). See Fig. 2. Therefore, it would have been obvious to one of ordinary skill in the art to provide the stimulation assembly as disclosed by Benja-Athon with an electronics bay as taught by Chung in order to support the circuitry that controls the electric current as disclosed by Benja-Athon (col. 4, lines 2-7).

In regards to claims 25 and 26, Benja-Athon, Chung and Lathrop discloses a method for providing neuromuscular stimulation function includes a function selected from a group comprising (i) maintenance of muscle function; (ii) tissue or bone regeneration; (iii) continuous active motion therapy; (iv) anti-scarring treatment; (v) diagnostic assessment; (vi) neuroplasticity therapy; (vii) anti-spasm therapy; (viii) pain therapy; (ix) post-surgical reconditioning; (x) anti-thrombosis therapy; and (xi) treatment of osteoporosis. Benja-Athon discloses a device for the treatment of pain and inflammation, which relates to (viii) pain therapy (col. 1-2). Chung discloses a device for stimulation the circulation of blood, which relates directly and indirectly to i-xi (col. 1). Lathrop discloses a device for prevent of lesions which is relates to (iv) anti-scarring treatment (col. 1).

Allowable Subject Matter

13. Claims 7-10, 13-16, and 18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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14. Claims 22-24 are allowed.

Citation of Relevant Prior Art

15. The prior art made of record and not relied upon include Cazuax et al. (U.S. Patent No. 5,957,951), Benja-Athon (U.S. Patent 5,857,968), Sanchez-Rodarte (U.S. Patent 6,016,451) and Swing (U.S. Patent No. 5,861,016) are considered pertinent to applicant's disclosure as neuromuscular stimulators.

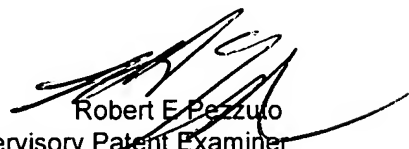
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shevon E. Johnson whose telephone number is (571) 272-2010. The examiner can normally be reached on M-F (8 a.m. - 4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SJ 11/7/2005


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766